

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA**

ANNABEL DOBBS,
Individually and as
Personal Representative of the
Estate of TERRY DOBBS, Deceased,

Plaintiff,

v.

WYETH,

Defendant.

NO. 04-CV-01762-D

**DEFENDANT WYETH'S RENEWED MOTION AND
OPENING BRIEF IN SUPPORT OF MOTION IN LIMINE TO PRECLUDE
KEITH ALTMAN, AN UNDISCLOSED EXPERT, FROM TESTIFYING**

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INTRODUCTION

On July 17, 2007, Wyeth moved to preclude testimony from Keith Altman on two grounds. First, any testimony that Altman might offer would be expert testimony about which plaintiff had made no expert disclosures. Second, even if plaintiff planned to call Altman solely to offer fact testimony, she identified him too late. (Doc. No. 115.) Plaintiff responded that Altman will offer no expert opinions and will present only Rule 1006 evidentiary summaries. (Pl's Resp. to Wyeth's Motion in Limine to Exclude K. Altman at 1–2; Doc. No. 131.)

On September 13, 2007, this Court held that Altman will not be “permitted to offer expert opinion testimony at the trial of this matter” because plaintiff had failed to comply “with the expert witness disclosure requirements” established by the Federal Rules of Civil Procedure and related deadlines imposed by the Court’s scheduling orders. (9/13/2007 Order at 2–3, Doc. No. 143.) The Court, at that time, declined to preclude Altman from offering lay testimony. Instead, the Court granted Wyeth leave to depose Altman to discern whether the testimony he would offer at trial was, in actuality, lay or expert. (*Id.* at 6–7.) If a fuller record indicated that Altman truly would offer only fact testimony, the Court reasoned that the deposition would cure any prejudice from untimely disclosure. (*Id.* at 7.) But the Court reiterated that if the nature of “Altman’s testimony requires his designation as an expert witness, his testimony must be excluded,” and it invited Wyeth to renew its motion after taking Altman’s deposition. (*Id.* 6–7.)

Wyeth must now accept the Court’s invitation. Wyeth deposed Altman on September 25, 2007. The testimony that Altman plans to offer is expert testimony. That

it may be offered in connection with an evidentiary summary does not change its character or excuse plaintiff's failure to disclose it. Wyeth now renews its motion to exclude Altman's testimony.

ARGUMENT

I. Altman's August 30, 2007 Affidavit and His September 25, 2007 Deposition Confirm That What He Will Say At Trial Is Expert Testimony.

The 2000 amendments to the Federal Rules of Evidence sharpened the distinction between lay and expert testimony. The amendments added a new clause "(c)" to Rule 701. The new clause declares directly what lay testimony is not. Lay testimony in the form of opinions or inferences "is limited to those opinions or inferences" that are "(a) rationally based on the perception of the witness, (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue, and (c) *not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.*" Fed. R. Evid 701 (emphasis supplied). Rule 702 correspondingly explains that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue," then only "a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."

The advisory committee notes and Tenth Circuit case law explain the distinction. "[T]he distinction between lay and expert witness testimony is that lay testimony results from a process of reasoning familiar in everyday life, while expert testimony results from a process of reasoning which can be mastered only by specialists in the field." Fed. R. Evid. 701, 2000 advisory committee note (internal quotations omitted). The Tenth

Circuit put it this way: “[A] person may testify as a lay witness only if his opinions or inferences do not require any specialized knowledge and could be reached by any ordinary person.” *Lifewise Master Funding v. Telebank*, 374 F.3d 917, 929 (10th Cir. 2004).

Altman’s testimony comes from no process of reasoning that is “familiar in every day life” or to “any ordinary person.” Rather, he proudly considers himself to have “specialized knowledge” acquired and “mastered only by specialists in the field” of database analysis. His claimed “specialized knowledge” is even more particularized. It relates to FDA and pharmaceutical company adverse event reporting databases. His testimony is premised on this knowledge. It is expert testimony and must be excluded.

A. Altman Claims Credentialing Worthy of Expert Qualification.

In his affidavit submitted to the Court on August 30, 2007, Altman calls himself a “data analysis and discovery consultant.” (K. Altman Aff. at ¶ 3 (Doc. 131-2).) He explains that he has served as a “plaintiff’s expert” on electronic data matters, that he speaks “routinely” on “data analysis,” and that “[a]s a routine part of [his] business activities, [he] collect[s] and analyze[s] adverse event data from the Food and Drug Administration (“FDA”) and pharmaceutical companies.” (*Id.* at ¶¶ 5–7.) His “business activities” include multiple consultancies for lawyers suing drug and device manufacturers. (*Id.* at ¶ 3.) He claims to have “accumulated” large amounts of FDA data and to “have normalized” it into a “single database.” (*Id.* at ¶ 7.) Plaintiff surely would have cited these credentials in an effort to qualify Altman as one who could offer expert

testimony by virtue of his “knowledge, skill, experience, [or] training,” Fed. R. Evid. 702, had she not failed to disclose him as an expert witness.

B. Plaintiff Is Paying Altman For His Work.

Plaintiff is paying Altman’s firm \$225 per hour for his work on this file; \$325 per hour for testifying. (K. Altman Dep. at 74:21–77:11 (Exhibit 1).) Work for hire is what experts typically do. Lay witnesses are not paid for their testimony. *See Cook v. Rockwell Int’l Corp.*, No. 90-CV-181-JLK, 2006 WL 13171, *2 (D. Colo. Jan. 2, 2006) (excluding testimony from witness characterized as offering only “lay or fact testimony” where witness’s testimony was “based entirely on the paid scientific work he performed for” a party). Altman’s testimony here is based on the paid technical work he has performed for plaintiff’s counsel both in this case and in others. It is paid-for expert testimony, not lay testimony.

C. Altman Will Not Testify From Rule 602 Personal Knowledge.

Part of the reason that parties pay experts to do the work that they do is that experts typically apply technical knowledge and expertise to new facts or data pertinent to the case in which they are retained. Put differently, lay witnesses testify from personal knowledge, *see* Fed. R. Evid. 602; experts testify from acquired expertise and facts presented to them. Altman proposes to do the latter. Because he does, his testimony should have been disclosed along with that of plaintiff’s other experts.

In *Martinez-Perez v. Hyundai Motor Co.*, 440 F. Supp. 2d 57 (D.P.R. 2006), the court considered a motion much like the one brought here. Hyundai sought to call a witness with technical knowledge concerning how airbag systems electronically store

data and how that data can be accessed and described. The witness had downloaded data from an airbag system's electronic control unit onto a computer and anticipated testifying to what the downloaded data contained. Hyundai identified that witness only as a fact witness. Plaintiff moved to exclude his testimony. The court granted the motion. The court held that explaining how the system stores information, how it can be accessed, and what it contains is "the subject matter of expert testimony . . . derive[d] exclusively from formal education or specialized training not from ordinary personal observation." *Id.* at 70–71.

Altman's testimony here, more fully described below, also involves an effort to download electronic data onto a computer, to access it, and to describe the results of that work. It, too, is "derived exclusively from" his "specialized training" and not from any "ordinary personal observations." It is expert testimony.

D. The Work Altman Claims To Have Done Requires "Scientific, Technical, Or Specialized Knowledge," And Any Testimony About It Would Be Rule 702 Expert Testimony.

What Altman has done and what he plans to say on the stand is based on "scientific, technical, or other specialized knowledge." Fed R. Evid. 702. He was retained, paid, and plans to offer Rule 702 expert testimony.

While Altman leaves distinctly open the possibility that he will be asked to do additional work and that he may offer testimony that appears neither in his affidavit nor in the transcript of his recently completed deposition (K. Altman Dep. at 122:24–124:05; 209:08–21; 217:02–219:08 (Exhibit 1)), his affidavit and testimony reveal that what he claims to have done so far requires "scientific, technical or other specialized knowledge."

Altman's affidavit characterizes his work as "comput[ing] the number of suicidal (suicidal ideation, suicide attempts, and completed suicide) reports contained in both the FDA AERS database and the [Wyeth] S³ database," and "compar[ing]" his computations "to see if there is a difference between the number of reports in the possession of the FDA and the number of reports in the possession of the company." (K. Altman Aff. at ¶ 21 (Doc. 131-2); K. Altman Dep. at 293:04–07 (Exhibit 1) (confirming that his affidavit accurately describes his work to date).) But the computing and the comparing is expert work.

Plaintiff herself has conceded that "it takes someone with technical ability" to "navigate these databases and to extract pertinent information." (Pl's Resp. to Wyeth's Motion in Limine to Exclude K. Altman at 2; Doc. No. 131.) And plaintiff's counsel designated Altman as an expert in another case to do what he plans to do here: "to describe—talk about adverse event reporting, adverse event reporting systems, and to provide summary contents of the FDA adverse event database." (K. Altman Dep. 72:06–09 (Exhibit 1).)

Altman himself admits that he used technical "experience"—developed over 25 years, more than ten years of it working with adverse event databases—to decide which computations to perform and what comparisons to draw. (*Id.* at 34:24–35:08.) He applied his acquired technical experience and knowledge in at least three ways.

First, he had to ascertain how the FDA and Wyeth historically and currently "code" adverse events and to determine a time period for which any putatively valid comparative analysis of coded events could be undertaken. This is no small task. The

FDA and Wyeth each currently use a hierarchical dictionary of adverse event terms or “codes,” referred to as MedDRA, and Altman’s familiarity with these coding protocols assisted him in selecting codes at what he considers the appropriate “Preferred Term” level of the hierarchical dictionary. (*Id.* at 141:24–142:16.)

But the FDA and Wyeth did not always use this dictionary. Nor did they switch to it at the same time. Altman, therefore, had to select what he believes is an appropriate start date for his comparative analysis after evaluating the respective timing of FDA and Wyeth changes in their adverse event coding protocols from COSTART, a predecessor platform, to MedDRA, the current platform. (*Id.* at 99:14–105:05; 142:21–145:03.)

Second, Altman developed what he believes are appropriate assumptions and a valid methodology for identifying markers in the FDA’s and Wyeth’s differently configured databases for the three discrete types of adverse events on which he sought to retrieve data and for accurately extracting the appropriate data on those events. To do this, he had to formulate query logic and write queries that would access the appropriate tables and fields within the FDA’s AERS and Wyeth’s S³ databases and pull from the selected fields data on cases coded with the three MedDRA Preferred Terms of interest to him. (*Id.* at 106:10–115:20; 121:20–122:12.) This is not the work of a lay person.

Altman had to determine which tables and fields within the FDA’s AERS database and within Wyeth’s S³ database contain MedDRA Preferred Terms and which of those fields correspond to events reported for a single case. (*Id.* at 35:09–36:24; 37:21–39:13; 41:08–42:08; 70:05–71:13; 134:02–137:14.) He had to know that the AERS and S³ databases each may contain multiple entries for the same case, and he had to develop a

method of discerning the date on which one of his selected Preferred Terms was first applied to a case in each of the databases and whether the most up-to-date version of that case, or the “last best case,” still bore that first-applied code. (*Id.* at 106:18–110:11; 113:11–115:18.) He had to know what tables and fields may be “voided,” interpret the meaning of a “voided” field, and assess whether to include cases with voided information in his calculations. (*Id.* at 138:08–139:08; 139:19–140:10.) He had to know what tables and fields indicate that a case had been “canceled” and assess whether to include canceled cases in his analyses. (*Id.* at 139:09–23; 140:11–24.) Double- or under-counting is the obvious and real risk here.

Third, Altman used the assumptions and methodology just mentioned to make what he suggests are valid comparisons in the way the FDA and Wyeth track and count adverse events. Though he tells us he will testify mainly to numbers, his derived and comparative adverse event counts are meaningless if not corroborated by some foundation for the accuracy of the calculations on which they are based and for the fairness of the side-by-side comparisons he draws. And here is where the opinion in what he is trying to accomplish is made even plainer: He gets the numbers wrong. He testified that adverse event numbers that he listed in his affidavit in this case are wrong. (*Id.* at 44:06–45:15; 82:09–25.) He testified that adverse event numbers that he put in an affidavit in the *Ackermann* case were wrong. (*Id.* at 185:22–187:21.) And he testified that adverse event numbers that he supplied for a proposed stipulation in the *Giles* case were wrong. (*Id.*) He concedes that they were all wrong because of inadequacies in the

queries that he had formulated to extract information from Wyeth's S³ database. (*Id.* at 82:09–25; 187:06–21.)

What Altman claims to do requires expertise—expertise he apparently must further develop. What he plans to offer, flawed as it might be, is expert testimony. It must be excluded.

II. Rule 1006 Does Not Independently Authorize The Admission of Expert Testimony Or Relieve Plaintiff From Her Expert Disclosure Obligations.

Rule 1006 provides that “[t]he contents of voluminous writings, recordings, or photographs which cannot conveniently be examined in court may be presented in the form of a chart, summary, or calculation.” The rule speaks to the admission of summaries of tangible things. To date, the only “things” associated with Altman’s work in this case are adverse event reports. The chart that appears at paragraph 24 of his affidavit purports to reflect his conclusions and calculations regarding these reports.

But the chart and its contents are the product of work performed by a witness who claims and applied specialized technical expertise, and the foregoing discussion makes clear that any testimony he might offer regarding the chart—or the analyses conducted as a predicate to generating it—would be expert testimony. The data within the chart could not be authenticated or otherwise considered for admission in any other way.

“Rule 702 applies if Rule 1006 evidence is in the form of an expert opinion. This most likely would be the case where the Rule 1006 evidence is a calculation. Rule 702 requires that the proponent demonstrate, among other things, that the person who prepared the Rule 1006 evidence was qualified as an expert and that his opinion would assist the trier of fact.” Wright & Gold, *Federal Practice and Procedure: Evidence* § 8043

(2000). To say what Altman wants to say about his “calculations” would require plaintiff to “demonstrate” that Altman “was qualified as an expert and that his opinion would assist the trier of fact.” This Court has already ruled that if Altman’s testimony required his qualification as an expert, his testimony would be barred. His testimony requires just that, and barred it should be.

The 2000 amendment to Rule 701 “makes clear that any part of a witness’ testimony that is based upon scientific, technical, or other specialized knowledge within the scope of Rule 702 is governed by the standards of Rule 702 and the corresponding disclosure requirements of the Civil and Criminal Rules.” Fed. R. Evid. 701, 2000 advisory committee note. Its drafters prepared the amendment “to eliminate the risk that the reliability requirements set forth in Rule 702 will be evaded through the simple expedient of proffering an expert in lay witness clothing.” *Id.*

Though plaintiff and Altman now disclaim that he will offer expert opinions at trial, his calculations and anything he might say about them are his opinions. No matter how you dress them up, he is an expert witness and what he wants to say is expert testimony. Plaintiff did not meet the disclosure requirements for experts imposed by the Civil Rules and the deadlines imposed by this Court. Altman’s expert testimony must be excluded.

CONCLUSION

For these reasons and those set forth in its initial moving papers, Wyeth requests that the Court grant its renewed motion in limine to preclude Keith Altman, an undisclosed expert, from testifying.

Dated this 19th day of October, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of October, 2007, I electronically transmitted the attached document to the Clerk of Court using the ECF System for filing and transmittal of a Notice of Electronic Filing to the following ECF registrants:

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